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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,283	03/28/2001	Rosa Perez Gomariz	HERR 18.313	3628
26504 KAOTTEN MUCHIN ROSENMAN LLP 575 MADISON AVENUE NEW YORK, NY 10022-2585			EXAMINER	
			WEN, SHARON X	
			ART UNIT	PAPER NUMBER
			MAIL DATE	DELIVERY MODE
			07/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 09/762 283 GOMARIZ ET AL. Office Action Summary Examiner Art Unit SHARON WEN 1644 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 04/29/2008; 06/12/2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-9.14-16.18 and 19 is/are pending in the application. 4a) Of the above claim(s) 1-9.14.15.18 and 19 is/are withdrawn from consideration. Claim(s) is/are allowed. 6) Claim(s) 16 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) □ Some * c) □ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Diselesure Statement(s) (PTO/SB/CC)
 Paper No(s)/Mail Date

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Amilication

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DETAILED ACTION

Applicant's amendment to the claims, filed 04/29/2008, has been entered.

Claims 10-13 and 17 have been canceled.

Claims 1-9 and 14-16, 18-19 are pending.

2. Text of those sections of Title 35 U.S.C. not included in this Action can be found in a prior Action.

This Action will be in response to Applicant's Arguments/Remarks, filed 01/23/2008.

The rejections of record can be found in the previous Office Action.

 Claims 1-9, 14-15 and 18-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species there being no allowable generic claim.

Claim 16 is currently under examination as they read on method for treating inflammatory or autoimmune pathologies administering an agent wherein the elected species of inflammatory or autoimmune pathologies is rheumatoid arthritis and the agent is VIP or an analogue derivative thereof.

Priority

 In response to Applicant's comment for Priority suggesting that a typographical error was made in the Office Action, mailed 11/01/2007 regarding the priority date for claims 16-17, following is noted.

The domestic priority date for clam **16** is deemed the effective filing date of PCT/ES00/00197, i.e., 06/02/2000.

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For the record, <u>no</u> typographical error was made in the Office Action, mailed 11/01/2007. Claim 17 was not accorded to the priority date as that of the filing date of PCT/ES00/00197, i.e., 06/02/2000 because it contained New Matter as noted in the previous Office Action, mailed 11/01/2007.

In view of the cancellation of claim 17, the issue regarding priority for claim 17 is rendered moot.

5. Applicant's claim for foreign priority is acknowledged. Certified copies of foreign priority application, 9901235, submitted under 35 U.S.C. 119(a)-(d), filed 06/12/2008, have been placed of record in the file. The support for Applicant's claim for foreign priority <u>cannot</u> be determined because application 9901235 is in Spanish and no certified translation has been provided.

Drawings

6. Applicant's amendment to the drawings, filed 04/29/2008, has been entered.

Claim Rejections - 35 USC § 112 first paragraph

- 7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- The previous New Matter rejection under 35 USC 112 first paragraph has been withdrawn in view of cancellation of claim 17 in Applicant's amendment, filed 04/29/2008.
- The previous Written Description rejection under 35 USC 112 first paragraph has been withdrawn in view Applicant's amendment of claim 16, filed 04/29/2008.

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Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- Claims 16 stands rejected under 35 U.S.C. 102(a) as being anticipated by
 Takeba et al. (Arthritis and Rheumatism 1999 42:2418-2429, see entire document).

Applicant's arguments have been fully considered but have not been found persuasive essentially for reasons of record.

In response to Applicant's reliance on the English translation of relevant portion (provided below) of Spanish priority application 9901235 for priority date in order to antedate the prior art, the following is noted.

English translation of Spanish patent no. 2160495. Page 2, column 2, lines 9-15: Many cases of inflammatory and autoimmune diseases are caused by the activation of the wrong type of Th cells. Diseases such as rheumatoid arthritis, multiple sclerosis. Crohn's disease, graft versus host reaction and others are characterised by an activation of Th 1 cells.

The present claim is drawn to a method of treating inflammatory or autoimmune pathologies comprising administering VIP. The above cited English translation discloses etiology of inflammatory and autoimmune diseases but does <u>not</u> provide any teaching on treating the diseases. The disclosure of the English translation of the priority document is <u>not</u> sufficient in scope of disclosure, relative to the scope of the instant claim and the scope of teachings in the prior art. Therefore, the priority date for claim 16 is still the effective filling date of PCT/ES00/00197, i.e., 06/02/2000; and the prior art rejection under 102(a) by Takeba et al. stands for the reasons of record.

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In response to Applicant's assertion that Takeba is an improper reference since it is not one year prior to the priority date of claim 16, i.e., 06/02/2000, Applicant is reminded that claim 16 is rejection under 35 USC 102(a) as stated in the previous Office Action, mailed 11/01/2007.

Applicant's arguments have not been found persuasive.

Therefore, the rejection of record is **maintained** for the reasons of record as it applies to amended claim. The rejection of record is incorporated by reference herein, as if reiterated in full.

Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takeba et al. (*Arthritis and Rheumatism* 1999 42:2418-2429).

Applicant's arguments have been fully considered but have not been found persuasive essentially for reasons of record.

Applicant's argument and Examiner's rebuttal are essentially the same as the above section under 35 USC 102(a) (see above).

Applicant's arguments have not been found persuasive.

Therefore, the rejection of record is **maintained** for the reasons of record as it applies to amended claim. The rejection of record is incorporated by reference herein, as if reiterated in full

Conclusion

14 No claim is allowed

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 THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Sharon Wen, Ph.D./ Examiner, Art Unit 1644 July 21, 2008

> /Phillip Gambel/ Phillip Gambel, Ph.D., J.D. Primary Examiner Technology Center 1600 Art Unit 1644 July 21, 2008